

Attorney Docket No.: 022101-000230US
Client Reference No.: 21640-US3
Serial No. 10/815,480
Response to Action mailed June 5, 3006

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REMARKS/ARGUMENTS

Status of the Claims

Claims 28-33 and 40-50 are pending, and claims 1-27, 34-39, and 51-56 are withdrawn.

Claim 28 has been amended herein. These clarifying amendments introduce no new matter and support is replete throughout the specification as originally filed. Exemplary support for the amended claim can be found, e.g., on page 8 in paragraph [0087], on page 4 in paragraph [0107], and in claim 1.

These amendments are made without prejudice and are not to be construed as an abandonment of the previously claimed subject matter or agreement with any objection or rejection of record. Applicant respectfully requests that all of these amendments be entered.

Record of Interview Substance

The Applicant provides herewith the following interview summary to be made of record with respect to the subject application. The Applicant thanks the Examiner for the helpful interview (hereinafter, Interview). The substance of the Interview was as follows:

Participants: M. Franco Salvoza (Examiner), Zachariah Lucas (Examiner), and Christopher Sappenfield (Attorney)

Date of Interview: November 30, 2006

Interview Type: Telephonic

Exhibit shown or demonstration conducted: None

Claims discussed: Claim 28

Art discussed: The art of record

Agreement with respect to the claims discussed: Examiners agreed to consider claim 28 as amended herein and the accompanying remarks.

Identification of principal proposed amendments of a substantive nature discussed: To overcome the rejections of record, discussed amending claim 28 to further specify

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length ranges for the recited oligonucleotides.

General thrust of the Applicant's principal arguments: The art of record does not teach or suggest the oligonucleotides recited in claim 28, whether viewed individually or in the combination recited in claim 28.

General indication of any other pertinent matters discussed: Discussed the propriety of the restriction requirement.

General results or outcome of the interview: Examiners agreed to consider the amendments to claim 28 in view of the associated remarks provided herein.

Restriction Requirement

Applicant respectfully submits that the restriction requirement does not conform to the requirements of the governing law. In particular, alleging that a claim represents multiple "patentably distinct" inventions is a *de facto* rejection of the patentability of the claim, because the claim cannot issue as drafted. Therefore, the restriction requirement at issue does not conform to the requirements of 35 U.S.C. § 121 as expressly articulated by the C.C.P.A. Specifically, the C.C.P.A. stated that:

It is apparent that § 121 provides the Commissioner with the authority to promulgate rules designed to *restrict* an *application* to one of several claimed inventions when those inventions are found to be "independent and distinct." It does not, however, provide a basis for an examiner, acting under the authority of the Commissioner to *reject* a particular *claim* on the same basis.

In Re Weber, Soder and Boksay, 198 U.S.P.Q. 328, 331-332 (C.C.P.A. 1978). Further, in the very next case decided by the C.C.P.A., the court interpreted this as a *per se* holding noting that:

In *In re Weber* . . . decided of even date, this court holds that §121 does not provide a basis for rejection of a claim. To the extent that §121 was employed as a basis for rejection, that rejection is, on the authority of *Weber*, reversed.

In Re Haas 198 U.S.P.Q. 334, 336 (*In Re Haas II*) (C.C.P.A. 1978). See also, *In Re Haas* 179 U.S.P.Q. 623 (*In Re Haas I*) (C.C.P.A. 1973). The C.C.P.A. further clarified the rationale behind this rule stating that:

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As a general proposition, an applicant has a right to have each claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. Such action would not affect the rights of the applicant eventually to have each of the claims examined in the form he considers to best define his invention. If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on the merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner, rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification.

In Re Weber, Soder and Boksay, 198 U.S.P.Q. at 331 (emphasis supplied). Thus, as exemplified by the cases set forth above, the courts have expressly ruled that there is no statutory basis for rejecting a claim for misjoinder, despite previous attempts by the Patent Office to fashion such rejections. In short:

the discretionary power to limit one applicant to one invention is no excuse at all for refusing to examine a broad generic claim — no matter how broad, which means no matter how many independently patentable inventions may fall within it.

In Re Weber, Soder and Boksay, 198 U.S.P.Q. at 334.

Instead of improperly imposing a restriction requirement on a claim, the Office may limit initial examination to a "reasonable number" of species encompassed by the claim. See, 37 C.F.R. § 1.146. This practice strikes an appropriate balance between the administrative concerns of the Patent Office relating to unduly burdensome examinations, and the clear constitutional and statutory rights of an inventor to claim an invention as it is contemplated, provided the dictates of 35 U.S.C. § 112 are complied with. Specifically, the C.C.P.A. stated that:

An applicant is given, by the statute, the right to claim his invention with the limitations he regards as necessary to circumscribe that invention, with the proviso that the application comply with the requirements of §112. We have

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decided in the past that §112, second paragraph, which says in part "[t]he specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention," allows the inventor to claim the invention as he contemplates it.

In re Wolfrum, 486 F.2d 588, 179 U.S.P.Q. 620 (C.C.P.A. 1973). See, the MPEP at 803.02. See also, *In re Kuehl* 177 U.S.P.Q. 250 (C.C.P.A. 1973). Unlike a restriction requirement, a species election does not preclude an applicant from pursuing the original form of a claim in subsequent prosecution, nor does it force an applicant to file multiple divisional applications, which are incapable of capturing the intended scope of the application. It should be clear that the added costs of filing and prosecuting additional patent applications in view of the present restriction requirement does not strike an appropriate balance between the administrative concerns of the office and the Applicant's statutory and constitutional rights as inventors. This would be particularly burdensome for the Applicant mindful that this is the second restriction requirement asserted in this case.

In the instant case, pending claims 28-33 and 40-50, which correspond to elected Group IV, include only one independent claim, namely, claim 28. As discussed during the helpful Interview, claims 34-39, which each depend from claim 28, were included in Group II in the restriction requirement mailed February 7, 2006. Accordingly, if claims 28-50 are required to be divided among separate applications, the claims as drafted would never be considered on the merits. This clearly violates the constitutional and statutory rights of the Applicant to claim her invention as it was contemplated. This restriction requirement would render the Applicant incapable of capturing the scope of the invention. Stated otherwise, the referenced restriction requirement is tantamount to rejecting claims 34-39 on the basis that they allegedly represent "independent and distinct" inventions. The Office simply may not restrict dependent claims away from their relevant independent claims. As clearly noted by the courts, dependent claims provide a service to the public by increasing the wealth of technical knowledge disclosed in the patent and providing the public with clarified notice of the extent of the patent rights to be granted, consonant with the dictates of 35 U.S.C. § 112. There is no legitimate basis for restriction between independent and dependent claims, no matter how many statutory classes are involved. *In re Kuehl*, 177 U.S.P.Q. at 256. Indeed, restricting dependent from independent claims is simply a rejection of the form of the claims, because the only way to recapture the restricted claims is to re-write them in an alternate

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form. Accordingly, the restriction requirement at issue is an explicit example of the procedure absolutely and unequivocally forbidden by the courts. Because this restriction requirement is *per se* improper, Applicant respectfully requests that it be withdrawn and that the claimed invention be examined as it was contemplated.

Applicant further notes that the courts have explicitly held that improper restriction of a single claim is a decision under the jurisdiction of the Board of Appeals, and the Federal Courts. This is in contrast to simple administrative decisions regarding ordinary restriction requirements, which are not generally subject to Appellate review. *See, In Re Haas I, supra*. Because restriction of a single claim into multiple groups is tantamount to a rejection and a refusal to examine the claim as drafted, as articulated in *Haas I*, the Board of Appeals and the courts have jurisdiction over the decision. Accordingly, Applicant expressly reserves the right to appeal any decision that may be made regarding the present restriction requirement to the Patent Office Board of Appeals and to the Federal Circuit.

Applicant further traverses the restriction of the claims as asserted in the Action, because examination of the pending claims does not present an undue burden for examination. A restriction requirement, which is within the discretion of the Examiner, is made to avoid placing an undue examination burden on the Examiner and the Office. Where claims can be examined together without undue burden, the Examiner must examine the claims on the merits even if they are directed to independent and distinct inventions. *See, the MPEP at 803.01*. In establishing that an undue burden would exist for co-examination of claims, the Examiner must show that examination of the claims would involve substantially different prior art searches, making the co-examination burdensome. As discussed during the Interview, in view of the sequences included in claim 28, the Examiner has already effectively performed a prior art search of all of the sequences recited in all of the claims as originally filed. Thus, since there is necessarily significant overlap among the prior art searched, Applicant respectfully submits that it cannot reasonably be asserted that co-examination of all pending claims would present an undue burden.

For the reasons set forth above, Applicant respectfully requests that the restriction requirement in the present case be withdrawn. There is no statutory authority for imposing a restriction requirement on any particular claim. The courts have expressly held that the type of restriction requirement made by the Examiner is an improper rejection subject to Appellate

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review. Moreover, the courts have expressly held that an Examiner may not use 35 U.S.C. § 121 as a basis for rejection of a particular claim.

Claim Notes

The Action notes that a trademarked term is used in claim 47 and requests that it should be capitalized or accompanied by the TM or ® symbol. Applicant notes that the relevant term utilized in claim 47 is accompanied by the TM symbol. Accordingly, Applicant respectfully requests clarification.

Objection to the Specification

The Action objects to the specification for including the typo "ad" in the abstract. Applicant has herein amended the abstract paragraph without entering new matter to correct the typo to recite "and". Accordingly, Applicant respectfully requests that this objection be withdrawn.

35 U.S.C. § 103

The Action rejects various claims under 35 U.S.C. § 103 as allegedly being obvious. In particular, the Action rejects claims 28, 40, 41, and 48-50 over Erlich et al. (U.S. Pat. No. 6,040,166 in view of Beasley et al. and Lanciotti et al (2002) with Buck et al. in support, claims 29-33 over Erlich et al. in view of Beasley et al. and Lanciotti et al (2002) with Buck et al. in support in view of Will (U.S. Pat. No. 6001611), claims 42 and 47 over Erlich et al. in view of Beasley et al. and Lanciotti et al (2002) with Buck et al. in support in view of Rigler et al. (1998), and claim 44 over Erlich et al. in view of Beasley et al. and Lanciotti et al (2002) with Buck et al. in support in view of Lanciotti et al (2001).

There is only one independent claim among the rejected claims, namely, claim 28. Further, all of the remaining rejected claims ultimately depend from claim 28. As amended, claim 28 relates to a kit for the detection of a nucleic acid of a member of the Japanese encephalitis virus serogroup. The claimed kit includes a) a first oligonucleotide that comprises SEQ ID NO.:8; b) a second oligonucleotide that hybridizes to a nucleic acid of SEQ ID NO.:9; and c) a detectably-labeled third oligonucleotide that hybridizes to a nucleic acid of SEQ ID NO.:16, or the complement thereof in which the first and second oligonucleotide lengths are from 25 to 100 nucleotides, and the third oligonucleotide length is from 28 to 100 nucleotides.

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None of the cited art, whether viewed alone or in combination, teaches or suggests all of the limitations recited in claim 28 as clarified by amendment herein. To illustrate, the referenced accession numbers merely relate to relatively long genomic sequences that allegedly include one or more of the claimed oligonucleotides. In particular, accession number AF458358 allegedly relates to a sequence that is 395 nucleotides in length, whereas accession number AF317203 purportedly relates to a sequence that is 10972 nucleotides in length. In contrast, the oligonucleotides recited in claim 28 include nucleotide sequences that are, e.g., conserved between two or more members of the Japanese encephalitis virus serogroup and are at most 100 nucleotides in length. That is, the claimed oligonucleotides include sequences conserved between different strains or members of a serogroup or genus and accordingly, are useful, e.g., as primers or probes that may be employed to detect those different strains or members. See, e.g., paragraph [0107] and example 1 of the subject application. Unlike the claimed invention, the cited art fails to teach or suggest, e.g., the utility of these conserved regions. Instead, they merely disclose relatively large genomic sequences that lack any such teaching. Since the cited art fails to teach all of the limitations of claim 28 or even any of the claimed sequences individually, the Action has not established a prima facie case of obviousness with respect to that independent claim, any claim dependent therefrom, or any other claim as originally filed. Moreover, the cited art also fails to provide any suggestion or motivation to modify the cited art or to combine its teachings to achieve the claimed invention. Accordingly, as all of the claims of the subject application, whether pending or withdrawn, are non-obvious over the cited art, Applicant respectfully requests that all of these rejections be withdrawn.

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CONCLUSION

In view of the foregoing, the Applicants believe all claims of the subject application are in condition for allowance. The issuance of a formal notice of allowance at an early date is respectfully requested.

Applicants hereby request a three-month extension of time for responding to the Office Action. The Commissioner is authorized to charge the extension of time fee under 37 CFR 1.17, to Account No. 50-0812. The Commissioner is further authorized to charge any fee deficiency, or credit any overpayment, to Deposit Account No. 50-0812.

If the Examiner believes a telephone conference would be of further assistance, please telephone Christopher Sappenfield at 510-814-2786.

Respectfully submitted,

DATE: 5 DECEMBER 2006

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